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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	016770-007100US	5232

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EXAMINER	
ALI, SHUMAYA B	

ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Examiner grants this office action in response to the amendment filed on 6/6/07. Currently claims 20-28 are pending and claims 1-19 have been cancelled in the instant application.

Specification

Claims 20 and 24 are objected to because of the following informalities: in claim 20, line 8, recitation of "introducing an aerosolized medicament into the lower volume flow of gas", and in claim 24, line 10 recitation of "entraining the aerosolized surfactant into the second low volume gas flow", specification does not provide adequate support for the cited recitations. Examiner acknowledges that Applicant cited that "nebulizer 6 emits an aerosolized medicament 9 into gas flow 8" (see page 5, lines 12 and 13), and such statement shows surfactant is introduced at high volume gas flow (flow 8), not at the low volume gas flow as required by the claimed invention. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Riggs et al. US 5,355,872.

As to claim 20, Riggs discloses a method of respiratory therapy **(using the device of fig.1)** comprising the steps of providing a pressure-assisted breathing system having a pressure-generating circuit **(26)** and a respiratory circuit **(26')** adapted to be coupled to a patient interface device **(24)**, With respect to "providing the respiratory circuit with a lower volume flow of gas than the pressure generating circuit", the position of the nebulizer **(20)** in figure 1 of Riggs suggests that a negative flow inherent upon inhalation at the interface, thus would providing flow at the interface (respiratory circuit) somewhat lower than flow at the outlet of the pressure generating circuit. Furthermore, by manipulating the flow meter **(40)** of Riggs one can further control the flow at the respiratory circuit. Riggs further discloses the step of coupling the patient interface device to the patient's respiratory system **(see fig.1)**, and introducing an aerosolized medicament **(contained inside nebulizer 20)** into the lower volume flow of gas in the respiratory circuit to deliver the medicament to the patient's respiratory system **(see fig.1)**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-23, 25-26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riggs 5,355,872 in view of Davison GB 2,272,389.

As to claim 21, Riggs lack a vibrating aperture-type aerosol generator for aerosolizing the liquid medicament and a connector for connecting the nebulizer to the respiratory circuit so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. However, Davison teaches a vibrating aperture-type aerosol generator **(fig.2)** for aerosolizing the liquid medicament and a connector **(2)** for connecting the nebulizer to

the respiratory circuit **(32)** so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose **(page 2, lines 10-13).**

As to claim 22, Davison teaches the nebulizer comprises a reservoir **(14)** having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir **(page 2, lines 10-13).**

As to claim 23, Davison discloses a reservoir **(14)** having a variable capacity **(fig.2);** consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claim 24, Riggs discloses a method of delivering a surfactant medicament to a patient respiratory system which comprises the step first high volume gas flow **(via 26)** for maintaining continuous positive airway pressure in the system **(via 106),** a respiratory circuit **(26')** supplying a second flow of volume gas flow to a patient interface device. Riggs however lacks a CPAP system. However, Rigg's device is well capable of providing a continues positive airway pressure using 106. Riggs further lacks a vibrating aperture type nebulizer coupled to the respiratory circuit. However, Davison teaches a vibrating aperture-type aerosol generator **(fig.2)** for aerosolizing the liquid medicament and a connector **(2)** for connecting the nebulizer to the respiratory circuit **(32)** so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with

the rear face of the membrane as a single dose **(page 2, lines 10-13).** Riggs discloses whereby the patient breathes the aerosolized surfactant through the patient interface device **(col.14, lines 20-38).**

As to claim 25, Riggs lacks the surfactant is phospholipids. However, it is known in the art that the surfactant can have variety of composition including phospholipids. Furthermore, Riggs broadly discloses surfactant, however, it would have been obvious to select a particular composition of surfactant to meet patient's therapy requirement.

As to claims 26 and 28, Riggs lacks wherein 6-18% of the aerosolized surfactant is delivered to the patient and wherein the dose is equal to 10 mg or less of surfactant. However, the particular amount of each dose and the particular amount of aerosolized medicament that is delivered to a patient can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular amount including 6-18% and 10mg or less. Furthermore, the particular amount and concentration of medicament is dependent upon the particular medical needs of a patient and is adjusted accordingly.

As to claim 27, Riggs lacks the entire dose is delivered to the patient and the dose is equal to 10 mg or less of surfactant. However, Davison teaches the nebulizer comprises a reservoir **(14)** having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir **(page 2, lines 10-13).** Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Riggs in order to provide the dosing capacity as claimed for the purposes of delivering contents of medicament without the need to replenish the reservoir as taught by Davison.

Response to Arguments

Applicant's arguments with respect to claim 6/6/07 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/19/2007

Shumaya B. Ali
Examiner
Art Unit 3771

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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
8/20/07